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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,808	11/14/2003	Dave S.B. Hoon	89212.0014	4483

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,808	HOON ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, and 4-13, drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets, classified in class 435, subclass 6.

(Upon election of group I, Applicant must select a single marker gene from claim 2 (either MAGE-A3, Mart-1, MITF, TRP-2, or Tyrosinase) as each marker represents a separate invention and not a species.)

II. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising of MAGE-A3, GalNAct, MART-1, and PAX3, classified in class 435, subclass 6.

III. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising of MART-1, GalNAct, MITF, and PAX3, classified in class 435, subclass 6.

IV. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid

targets from a panel comprising of MART-1, TRP-2, GalNAct, and PAX3, classified in class 435, subclass 6.

V. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising of Tyrosinase, MART-1, GalNAct, and PAX3, classified in class 435, subclass 6.

VI. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas or colon cancer cells in a patient comprising preparing paraffin embedded samples from tissues or lymph nodes of the patient wherein the panel comprises C-Met, MAG-A3, GalNAct, and CK20, classified in class 435, subclass 6.

VII. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas or colon cancer cells in a patient comprising preparing paraffin embedded samples from tissues or lymph nodes of the patient wherein the panel comprises C-Met, GalNAct, and β-HCG, classified in class 435, subclass 6.

VIII. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas or colon cancer cells in a patient

comprising preparing paraffin embedded samples from tissues or lymph nodes of the patient wherein the panel comprises β-HCG, HSP27, and C-Met, and, classified in class 435, subclass 6.

IX. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas or colon cancer cells in a patient comprising preparing paraffin embedded samples from tissues or lymph nodes of the patient wherein the panel comprises HSP27, CK20, Stanniocalcin-1, and MAG-A3, classified in class 435, subclass 6.

X. Claims 23-26, drawn to a kit for use in detecting melanoma cells in a biological sample, classified in class 435, subclass 810.
(Upon election of group X, Applicant must select <u>one</u> marker gene from claims 24 (either MAGE-A3, Mart-1, MITF, TRP-2, <u>or</u> Tyrosinase) as each marker represents a separate invention and not a species.)

The inventions are distinct, each from the other because of the following reasons:

The invention of group X is a product, while the inventions of groups I-IX are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions X and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the primers from the kit can be used in the materially different process of affinity chromatography.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),"

1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species

Claims 9 and 20 are generic to a plurality of disclosed patentably distinct species comprising the following: **parameters**. The above species represent separate methods which differ at least in objectives and method steps such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER